ACR-AAPM TECHNICAL STANDARD FOR MEDICAL PHYSICS PERFORMANCE MONITORING OF PET/CT IMAGING EQUIPMENT

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care $\frac{1}{2}$. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do

I. INTRODUCTION

This technical standard was revised collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

Positron emission tomography/computed tomography (PET/CT) systems can be operated to acquire only PET images or CT images as well as PET/CT images, combining two medical imaging modalities: CT for both anatomical imaging and attenuation correction and PET for functional imaging. This brings the advantages and complexities of both systems while providing anatomical and functional aspects through fused images. All new PET/CT equipment must be tested on installation and must be monitored at least annually by a Qualified Medical Physicist to ensure proper functioning within the manufacturer's specifications and accepted performance standards. Additional or more frequent performance monitoring may be necessary in certain situations (eg, after major equipment maintenance).

Although it is not possible to consider all variations of equipment performance to be monitored, adherence to this technical standard will optimize image quality and ensure the accuracy of quantitative clinical results. Key points to consider are system performance characteristics, patient radiation dose, qualifications of personnel, radiation shielding, and follow-up procedures.

The primary goal of PET/CT imaging is to produce quantifiably accurate and spatially coregistered PET and CT images on the same platform. An additional goal is to produce images with the lowest radiation dose consistent with the clinical use of the equipment and the information requirements of the examination. The purpose of this document is to provide technical standards for medical physics oversight of PET/CT imaging equipment. The scope of these technical standards is limited to the PET subsystem of PET/CT systems used for diagnostic imaging. Technical standards for the CT subsystem are published in a separate document [1]. PET/CT systems used for specialized tasks, such as radiotherapy dosimetry calculations, may require additional quality management (QM) beyond that described in this document.

II.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A Qualified Medical Physicist must carry out acceptance testing and monitoring of PET/CT equipment.

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u> [2].

The appropriate subfield of medical physics for this technical standard is Nuclear Medical Physics (including medical physics certification categories of Radiological Physics and Medical Nuclear Physics and Nuclear Medicine Physics) with continuing medical education in CT physics.

or

Diagnostic Medical Physics (including medical physics certification categories of Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics) with continuing education in PET imaging physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

The Qualified Medical Physicist must be familiar with the principles of imaging physics and radiation protection; the guidelines of the National Council on Radiation Protection and Measurements (NCRP); the laws and regulations pertaining to the use of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and the calibration processes and limitations of the instruments and the techniques used for testing performance.

The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data. These individuals must be approved by the Qualified Medical Physicist and be trained in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The Qualified Medical Physicist is responsible for and must review, interpret, and approve all data and must provide a signed report with conclusions [3].

III.

PERFORMANCE CHARACTERISITICS TO BE MONITORED

A. Acceptance Testing

Initial performance testing of newly installed imaging equipment must be performed by a Qualified Medical Physicist and should be completed before clinical use. This testing should be more comprehensive than periodic performance testing and must be consistent with current acceptance testing practices [4,5]. Electrical safety of the equipment must also be tested by appropriate personnel prior to its initial clinical use.

If a major component is replaced or repaired, a Qualified Medical Physicist should, in a timely manner, evaluate the need for performance testing of the PET/CT scanner. The scope of the evaluation should be determined by the Qualified Medical Physicist based on the type of component that was replaced or repaired.

B. Performance Evaluation

 The Qualified Medical Physicist must design a QM program that includes regular quality control (QC)/quality assurance (QA) procedures to ensure proper daily operation. The procedures should include daily QC tests as well as quarterly scanner testing to evaluate image uniformity, image spatial resolution, standardized uptake value (SUV) or activity concentration in becquerel (Bq/cc) accuracy, and image contrast.

The following characteristics should be evaluated on at least an annual basis as applicable to the design of the scanner:

- a. Count rate performance (count rate versus activity), including corrections for count losses and random coincidences
- b. Sensitivity
- c. Image uniformity and artifact assessment
- d. Image spatial resolution
- e. Image contrast
- f. Accuracy of CT-based attenuation and scatter correction, and SUV or activity concentration
- g. Image coregistration between PET and CT
- h. Safety evaluation
 - i. Mechanical
 - ii. Electrical

Guidance in performing these tests is available from several sources [4-6]. The Qualified Medical Physicist should decide how the tests should be performed for each system they survey.

Overall PET/CT imaging performance is affected by the individual and the joint performance of the PET and CT subsystems. Performance evaluations should test each subsystem individually and together.

C. Quality Management Program

A QM program must be established for all PET/CT systems with the assistance of a Qualified Medical Physicist consistent with the recommendations of this document, the <u>ACR-ACNM-SNMMI-SPR Practice</u> <u>Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures</u> [7], and the <u>ACR-AAPM Technical</u> <u>Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT)</u> <u>Equipment</u> [1]. The Qualified Medical Physicist should determine tolerances, the frequency of each QC/QA procedure and who should perform each QC/QA procedure based on the facility, PET/CT usage, and the equipment manufacturer's requirements and recommendations. An on-site technologist should be identified to be responsible for conducting routine QC/QA [1,7].

The results of the QM program must be monitored at least annually by the Qualified Medical Physicist. If measured values of QC/QA parameters fall outside the established tolerances, the QC/QA technologist should consult with the Qualified Medical Physicist. The Qualified Medical Physicist should recommend or, when appropriate, initiate investigative or corrective actions. A Qualified Medical Physicist should be available to assist in prescribing corrective actions for unresolved problems.

D. Written Survey Reports and Follow-Up Procedures

The Qualified Medical Physicist must provide a written report of the findings of acceptance testing and a performance evaluation to the professional(s) in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the responsible physician(s). Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

If appropriate, the Qualified Medical Physicist should notify the facility to initiate the required service. The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from competent service personnel as verification that the issue(s) were appropriately resolved. The reports may be reviewed by a Qualified Medical Physicist to confirm that the equipment is performing in a safe and acceptable fashion after the required service is performed or as required by federal, state, or local regulations.

If use of the equipment would pose a danger to life or health or potentially result in erroneous clinical findings, the Qualified Medical Physicist in collaboration with the facility's Radiation Safety Officer and interpreting physician must take immediate action to either prevent equipment use or to indicate in writing what limited studies can be performed safely using the equipment until the hazard is addressed.

IV. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-publicae.org/MTCD/Publications/PDF/PUB1775_web.pdf

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals in accordance with ALARA principles. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by applicable state, local, or other relevant regulatory agencies and accrediting bodies, as appropriate. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol, using body habitus or other customized method when such guidance is available.

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>[®], should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently[®] for children (<u>www.imagegently.org</u>) and Image Wisely[®] for adults (<u>www.imagewisely.org</u>). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

v.

RADIATION SHIELDING CONSIDERATIONS

Special care must be exercised regarding radiation shielding requirements for PET/CT facility design. Appropriate shielding must be provided for patient injection/uptake rooms, PET/CT imaging suites, hot labs, and any other areas where PET radiopharmaceuticals are produced, prepared, used, disposed, or stored. Due to the high energy of annihilation radiation used in PET, the amount and type of shielding materials needed to protect adjacent areas is typically different from that of X-ray or conventional nuclear medicine. A Qualified Medical Physicist should be consulted early in facility design planning stages so that shielding requirements can be determined and structural design issues, created from using the larger amounts of shielding, can be assessed. The AAPM Task Group 108 report "PET and PET/CT Shielding Requirements," [17] in conjunction with the National Council on Radiation Protection Report 147, should be used as a reference in determining PET/CT shielding requirements.

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Standards – Medical Physics of the ACR Commission on Medical Physics in collaboration with the AAPM. <u>Writing Committee</u> – members represent their societies in the initial and final revision of this technical standard

ACR	AAPM
Samuel A. Einstein, PhD, Chair	David W. Jordan, PhD
Kenneth G. Lewis, II, MS, PhD	
Osama Mawlawi, PhD, FACR	
Keisha C. McCall, PhD	
Alok Shankar, PhD	
Committee on Practice Parameters and Technical Standards – Medical Physics	
(ACR Committee responsible for sponsoring the draft through the process)	
Mary Ann Keenan, DMP, Chair	Samuel A. Einstein, PhD
Katherine P Andriole, PhD, FACR	Ralph P. Lieto, MSE, FACR
Eric A. Berns, Ph.D, FACR	Osama Mawlawi, PhD, FACR
Courtney R. Buckey, PhD	Matthew A. Pacella, MS, FACR
Diana E. Carver, PhD	Ashley E. Rubinstein, PhD
Heidi A. Edmonson, PhD	Russell B. Tarver, MS

Mahadevappa Mahesh, MS, PhD, FACR, Chair, Commission on Medical Physics David B. Larson, MD, MBA, FACR, Chair, Commission on Quality and Safety Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Andrew K. Moriarity, MD, Chair	David B. Larson, MD, MBA, FACR
Maxwell R. Amurao, PhD, MBA, Co-Chair	Paul A. Larson, MD, FACR
Bradley Beattie, MS	Kenneth G. Lewis, II, MS, PhD
Timothy A. Crummy, MD, MHA, FACR	Mahadevappa Mahesh, MS, PhD, FACR
Samuel A. Einstein, PhD	Osama Mawlawi, PhD, FACR
William Erwin, MS	Keisha C. McCall, PhD
Mary Ellen Jafari, MD, FACR	Mary S. Newell, MD, FACR
David W. Jordan, PhD	Charles Schmidtlein, PhD
Mary Ann Keenan, DMP	Alok Shankar, PhD
Amy L. Kotsenas, MD, FACR	Roland Wong, ScM

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*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association of Physics in Medicine are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 54, 2015). The effective date is the first day of the month following a 60-day period that begins on the date the document was approved.

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